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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,103	10/14/2005	Andrei Bugrim		5310

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,103	BUGRIM ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10 and 13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10 and 13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 July 2010 has been entered.

Claim Status

Claims 1, 3, 5-10, 13-25 are pending.

Claims 2, 4, and 11-12 are cancelled.

Claims 13-25 are new

Claims 1, 3, 5-10, 13-25 have been examined.

Claims 1, 3, 5-10, 13-25 are rejected.

Priority

This application was filed on 14 October 2005 under 35 USC 371 as the national stage of PCT/US03/19325, which was filed on 18 June 2003 and claims the priority of US provisional Application No. 60/389474, which was filed on 18 June 2002. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first

paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/299,040 filed on 18 June 2001, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A review of earlier filed US Provisional Application No. 60/299,040 reveals the earlier filed disclosure is silent with regards to the steps of ranking and generating structured annotations as claimed in the amendment of 13 July 2010.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 1, 3, 5-10, and 13 -25 as reciting new matter under 35 USC 112, First paragraph is withdrawn in view of the amendment to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26-28 is unclear with respect to the phrase “a multi-step mammalian pathway”. The metes and bounds of the claim are rendered indefinite by the lack in clarity. It is unclear from the claim how the source of the claimed pathways are differentiated as mammalian or non-mammalian from data alone. Many metabolic

pathways are shared among organisms. The identification of a pathway in and of itself does not indicate the organism source. For example, the Krebs cycle is a multistep metabolic pathway. However, the name Krebs cycle does not give any indication of whether the source organism was E. coli, C. elegans, or H. sapiens. The claims are directed to product comprising instruction to enable a method comprising collecting data and linking the data into pathways. The claim does not indicate what information or data is collected and how it is related. Moreover, it is unclear how a non-mammalian pathway is obtained from data regarding human metabolism. Thus it is unclear from the claim that the data is assembled in such a way to indicate the source of the pathway. The claim is being interpreted, for the purpose of examination, as directed to assigning each pathway to a category selected from the group consisting of i) a pathway in which all reactions are catalyzed by a known enzyme; ii) a pathway comprising a reaction is catalyzed by an enzyme that is predicted, but has not been identified ; iii) a single step pathway.

Claim 26-28 is unclear with respect to the phrase “is not catalyzed by a human enzyme”. The metes and bounds of the claim are rendered indefinite by the lack of clarity. It is unclear from the claim what applicant intends to encompass by the claimed limitation. If applicant intended to direct the limitation to a pathway comprising a reaction is catalyzed by an enzyme that is predicted, but has not been identified, then an amendment would be appropriate.

Claim Rejections - 35 USC § 102

Response to Arguments

The rejection of claims 1, 3, 5-10, and 13-25 as anticipated by Buechler et al. under 35 USC 102(b) is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claims 1, 3-5, 7-10, 13, 15-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000), in view of Forst et al. (JOURNAL OF COMPUTATIONAL BIOLOGY Volume 6, Numbers 3/4, 1999, Pp. 343–360) and van Heyningen (Molecular Medicine, Volume 3, Number 4, April 1997. 231-237), in view of Ishizuka et al. (Information processing society of Japan, Vol. 91, p. 73-80, 27 September 2000) and in view of Takai-Igarashi et al. (In Silico Biology, Vol. 1, p. 129-146, 1999).

The claims are directed to a method for reconstruction of the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; ranking metabolic pathways based on relevance to human metabolism; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows data is linked to metabolic pathways and that inter-connections are identified to create a map of the organism's metabolism (figure 4). Nakao et al. shows that the metabolic reconstruction also comprises data regarding metabolism of an organism for

both a reference (non-diseased) and perturbed (diseased) state (p. 95). Nakao et al. refers to reference and perturbed states, and the KEGG database actually contains data related to diseased and non-diseased states in humans (see the KEGG database table of contents from February 1999) Nakao et al. shows that pathway maps can be reconstructed for eukaryotes such as fruit fly, mouse, human, and Saccharomyces cerevisiae.

Nakao et al. does not show the identification of drug targets or interactive map is created.

Karp et al. shows that drug targets can be identified through the analysis of pathway genome databases (p. 278, col. 2 to p. 279, col. 1). Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery (abstract).

Kuffner et al. shows a method of that combines the information found on various metabolic databases to produce a differential metabolic display (DMD). The DMD of Kuffner et al. allows the comparison between disease pathways and non-disease pathways (p. 825, col. 2-p. 825, col. 1). Kuffner et al. suggests differences can be identified from the comparison. Kuffner et al. shows that the data to generate DMD's are taken from such databases as KEGG (p. 826, col. 1). Kuffner et al. shows the type of data obtained from the databases comprises biochemical units further comprising metabolic steps (enzymes), chemical compounds (ligands, cofactors, substrates, and products), reactions, and enzymatic function(genes and proteins) (p. 826, col. 2 and figs1 and 5). Kuffner et al. shows an annotation table comprising fields such as sub

cellular localization and intracellular compartmentalization (figure 5). Kuffner et al. suggests that DMD will useful for target identification (abstract). Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of unknown function and to propose the existence and/or absence of specific proteins or protein functions (p. 834, col. 2).

Forst et al. shows a method of comparing metabolic pathways. Forst et al. shows that distance measure can be generated between any two organisms of interest similar to the comparison of biopolymer sequences (fig. 1 and p. 344). Forst et al. shows advantageously the relation of pathways of different organisms to each other by phylogenetic analysis, extending conventional phylogenetic analysis of individual enzymes to providing a more comprehensive understanding of similarities and differences between organisms (abstract).

Forst et al. does not show the relevance to human metabolic pathways.

van Heyningen shows model systems contribute to the understanding of human disease (p. 231, col. 1). van Heyningen shows that model research organisms reveal an amazing degree of conservation among genes that participate in similar pathways in humans (p. 231, col. 1). van Heyningen provides an example relevance of model organism pathways have to humans by describing the conservation of DNA proofreading and repair between Humans and model organisms, such as bacteria and yeast (p. 232, col. 2). van Heyningen shows there is much two-way traffic between different model systems, allowing the unraveling of complex interactive pathways and it

is becoming increasingly clear that these pathways are generally highly conserved, so that analysis in one system can be extrapolated to another with sufficient confidence, at least to suggest novel experiments to check out the expected homology (p. 235, col. 1). Thus, van Heyningen shows that the metabolic pathways between other organisms and humans is conserved to extent to be relevant to human metabolism.

Ishizuka et al. shows the construction of an interactive metabolic pathway map (p. 73). Ishizuka et al. shows the interactive map provides the advantage of presenting fundamental knowledge in biology and biochemistry (p. 73).

Takai-Igarashi et al. shows a process of reconstructing pathways. Takai-Igarashi et al. shows that data is collected regarding human metabolism in a database, reading linked data regarding human metabolism exclusively used to create the interactive map (p. 130). Takai-Igarashi et al. shows biochemical units comprising chemical compounds reactions, metabolic steps, and enzymatic functions (p. 145). Takai-Igarashi et al. shows enzymatic functions comprise genes and proteins (p. 145). Takai-Igarashi et al. shows an annotation table with at least one field (p. 136). Takai-Igarashi et al. shows a field showing organ/tissue localization (p. 135 and 145). Takai-Igarashi et al. shows that in humans, metabolic pathways are more complex than other phyla such as bacteria due to the interconnections between pathways that are considered important for the evolution of elaborate mechanisms that enable individual cells to communicate with one another to coordinate behavior for the benefit of the whole organism (p. 130).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of reconstructing an organism's metabolism of Nakao et

al. with the drug target identification of Karp et al. because Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery. It would have been further obvious to modify the method of reconstructing metabolism with collected data of Nakao and the use of pathways to identify targets of Karp et al. with the DMD's of Kuffner et al. because Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of unknown function and to propose the existence and/or absence of specific proteins or protein functions.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the reconstruction of a mammalian, or any organism's, metabolic pathway map of Nakao et al., in view of Karp et al., and in view of Kuffner et al. with the algorithm for ranking a model pathway from one organism to a pathway of another organism of Forst et al. because Forst et al. shows advantageously the relation of pathways of different organisms to each other by phylogenetic analysis, extending conventional phylogenetic analysis of individual enzymes to providing a more comprehensive understanding of similarities and differences between organisms. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the reconstruction of a mammalian, or any organism's, metabolic pathway map of Nakao et al., in view of Karp et al., in view of Kuffner et al., and in view of Forst with to score the pathways of model organisms relative to human pathways as suggested by van Heyningen who shows there is much two-way traffic between different model

systems, allowing the unraveling of complex interactive pathways and it is becoming increasingly clear that these pathways are generally highly conserved, so that analysis in one system can be extrapolated to another with sufficient confidence, at least to suggest novel experiments to check out the expected homology. Thus, van Heyningen shows that the metabolic pathways between other organisms and humans is conserved to extent to be relevant to human metabolism. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the reconstruction of a mammalian, or any organism's, metabolic pathway map of Nakao et al., in view of Karp et al., in view of Kuffner et al., and in view of Forst et al. and van Heyningen with the interactive metabolic pathway map of Ishizuka et al. because Ishizuka et al. shows the interactive map provides the advantage of presenting fundamental knowledge in biology and biochemistry. It would have been further obvious to one of ordinary skill in the art to further modify the method of metabolic reconstruction of Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, and in view of Ishizuka et al. by creating a map exclusively from human data as shown by Takai-Igarashi et al. because Takai-Igarashi et al. shows that in humans metabolic pathways are more complex than other phyla such as bacteria due to the interconnections between pathways which are considered important for the evolution of elaborate mechanisms that enable individual cells to communicate with one another to coordinate behavior for the benefit of the whole organism.

Response to Arguments

Applicant's arguments filed 13 July 2010 have been fully considered but they are not persuasive. Applicant argues Nakao et al., in view of Karp et al., in view of Kuffner et al. in view of Ishizuka et al., and in view of Takai-Igarashi et al. fails to show the limitations of the claims as instantly amended. The argument is not persuasive. Forst et al shows a method of ranking metabolic pathways between organisms. van Heyningen shows that the metabolic pathways between other organisms and humans is conserved to extent to be relevant to human metabolism.

Claim 6, 14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000) as applied to claims 1, 3-5, 7-10, 13, 15-20, and 22-25 above, and further in view of Okubo et al. (Nature Genetics, Vol. 2, p. 173-179, November 1992).

Claims 6 and 14 are directed to data that is Expressed sequence tag (EST) data.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1 and 3, 5 above teach a method of metabolic reconstruction.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, 15-20, and 22-25 above do not show EST data.

Okubo et al. shows expression data that comprises EST data can be used in mapping (p. 178, col. 1). Okubo shows the advantage of using expressed sequence tags results from a comparison of data from the same cells under different physiological conditions that will aid in the understanding of cell- and time-dependent control of gene expression (p. 176-177, col. 2). Okubo et al. shows that maps of expressed genes will help in the search for biologically and industrially interesting genes (p. 173, col. 1).

It would have been obvious to one of skill in the art at the time of invention to modify the method of metabolism reconstruction of Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, and 15-18 above with the incorporation of EST data of Okubo et al. because Okubo et al. shows that a map of expressed genes will facilitate the search for biologically and industrially interesting genes.

Response to Arguments

Applicant's arguments filed 13 July 2010 have been fully considered but they are not persuasive. Applicant argues that Okubo et al does not cure the deficiencies of Nakao et al., in view of Karp et al., in view of Kuffner et al. in view of Ishizuka et al., and in view of Takai-Igarashi et al. The argument is not persuasive for the reasons provided above. Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, in view of Ishizuka et al. and in view of Takai-Igarashi et al. shows the elements of the instantly claimed invention.

The following rejection is new.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, in view of Ishizuka et al., and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, 15-20, and 22-25 above, and further in view of Schilling (PG PUB 2003/0233218).

The claims are directed to assigning each pathway to a category selected from the group consisting of i) a pathway in which all reactions are catalyzed by a known enzyme; ii) a pathway comprising a reaction is catalyzed by an enzyme that is predicted, but has not been identified; iii) a single step pathway.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, in view of Ishizuka et al., and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, 15-20, and 22-25 show a method of reconstructing human metabolism.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, in view of Ishizuka et al., and in view of Takai-Igarashi et al. do not show assigning pathways to categories.

Schilling shows a method of reconstructing metabolic models. Schilling shows that a reaction catalyzed by an enzyme from a pathway is assigned a confidence value base on the amount of evidence supporting the reaction, indicating the reactions relevance [0134]. Schilling shows the introduction of confidence levels enhances model specificity and provides the advantage of maintaining quality control and accountability for the content of the model [0127].

It would have been obvious to one of ordinary skill in the art to modify the method human metabolic reconstruction of Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Forst et al. and van Heyningen, in view of Ishizuka et al., and in view of Takai-Igarashi et al. as applied to claims 2, 4, 6 and 9-13 with the determination of confidence levels for intermediate reactions of Schilling because Schilling shows the introduction of confidence levels enhances model specificity and provides the advantage of maintaining quality control and accountability for the content of the model. One of ordinary skill would have been motivated to modify the teachings of Schilling, Nakao et al., in view of Karp et al., in view of Kuffner et al., Forst et al., Ishizuka et al., and Takai-Igarashi et al. by van Heyningen who shows that metabolic pathways found in humans are also conserved in other eukaryotes, like C. elegans and S. cerevisiae, and in prokaryotes. van Heyningen shows that the pathway for apoptosis or programmed cell death are conserved between human and C. elegans (p. 233, col. 1). Thus the showing of conservation metabolic pathways among humans and organisms of different phyla would have motivated one to apply the similar techniques of collecting, mapping, linking, ranking, annotating, and identifying interconnections as described by Schilling, Nakao, Forst et al., Ishizuka et al., and Takai-Igarashi et al. to human metabolism.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This rejection is reiterated from the previous Office Action.

Claims 1, 3, 5, 7-10 13, 15-20 and 22-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10of copending Application No. 11/499, 437. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of copending Application No. 11/ 499,437 are similarly directed to methods of reconstructing metabolic pathways from collected data and comparing pathway data in a diseased state to data in a non-diseased state. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 are directed to the same use, namely to identify drug targets. Claim 1 of Application no. 11/499,437 is alternatively directed to identifying gene therapy targets. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 perform the same steps and produce the same result. In addition, claims 15 and 16 of the instant application are directed to further limitation of the data specifically chemical compounds, reading on

metabolite of as recited in claim 4 of Application No. 11/499,437, and proteins, also as recited in claim 4 of Application No. 11/499, 437. The claimed inventions also have embodiments in which the data is heterogeneous and directed to humans. The claimed inventions also recite embodiments comprising annotation tables directed to localization information.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following double patenting rejection is maintained from a previous action and has been amended as necessitated by amendment.

Claims 1, 3, 5-10, 13-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-19 of copending Application No. 10/174,762. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to the reconstruction of metabolic pathways of an organism. Both claimed inventions rely on the collection of data regarding an organism's metabolism; linking the data into metabolic pathways and identifying interconnections between metabolic pathways. The claimed inventions also have embodiments in which the data is heterogeneous, expressed sequence tag data, and directed to humans. The claimed inventions also recite embodiments comprising annotation tables directed to localization information.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Primary Examiner, Art Unit 1631

16 August 2010